AMENDMENTS

In the Specification:

Please replace paragraph [0065] with the following amended paragraph:

[0065] If the user has chosen to access more details, then the user is preferably presented with muliple dimensions of the risk assessment from which to access more information. Preferred dimensions of risk assessment include, but are not limited to, Reactions More Details Box ~~115~~ 116, Concomitant Drugs More Details Box ~~116~~ 117, Demographics More Details Box 118, Report Dates More Details Box ~~118~~ 119, and Outcomes More Details Box 120.

Please replace paragraph [0066] with the following amended paragraph:

[0066] Preferably, if the user has chosen to filter in various dimensions of risk assessment, then the user is preferably presented with multiple filters for the dimensions of the risk assessment. Preferred filters of dimensions of risk assessment include, but are not limited to, Reactions Filters Box ~~121~~ 122, Concomitant Drugs Filters Box ~~122~~ 123, Demographics Filters Box ~~123~~ 124, Report Dates Filters Box 125, and Outcomes Filters Box 126.

Please replace paragraph [0067] with the following amended paragraph:

[0067] The preferred components of the present invention are illustrated in Figure 2, which provides an overview of the system and method of the present invention. The user preferably accesses the system of the present invention by means of Home Page 200. From Home Page 200 the user can proceed to the Selector 201, where the user can select a drug for analysis. Having selected the drug of interest, the user can then preferably proceed to the Profiler 202, which

preferably displays statistics that describe the behavior of the drug of interest. From the Profiler 202 the user can then preferably proceed to employ one or more Filters 203, which permit recalculation of the statistics by selecting among the available variables. Once a set of cases is determined, for example, by the use of one or more filters, the cases can then preferably be submitted to at least one of three or more Data Mining Engines 204. The output form the data mining engines is then preferably displayed in a Viewer 205, which can present the data in a variety of formats, including, but not limited to a sortable table, a sortable line listing, and a radar screen, thus, allowing rapid identification of signals and providing the user the ability to drill down to individual case details.

Please replace paragraph [0092] with the following amended paragraph:

[0092] An exemplary Query Screen page is illustrated in Figure 5, where a user has decided to search the therapeutic category of angiotensin converting enzyme (ACE) inhibitors, as defined by the drug dictionaries. (Note: In this case the FDA taxonomy places certain drugs known as ATII drugs in the ACE category). Here, the user has chosen not to use the generic name field 500 or the trade name field 501, but rather has chosen the therapeutic category field 503. The present system returns with the hits corresponding to the selected therapeutic category and are displayed in the query screen. In this example, ~~22~~ 4 drugs matching the search criteria were found in the "ACE Inhibitors" category. The drugs are listed in alphabetical order by their generic name. For each generic drug on the list, all trade names and all relevant therapeutic categories are presented in pull-down menus. Optionally, custom-defined categories can also be shown. The search results also allow access to the drug's "pedigree," or lexical mapping information, indicated by a question mark link.

Please replace paragraph [0097] with the following amended paragraph:

[0097] The key explains the types of processing that the system and method of the present invention performs to standardize drug names and to improve the quality of the reported data. The present invention preferably performs five types of processing: spelling correction (corrects misspelled drug names and standardizes variations in drug names), noise words (works like, for example, "tablets" "Prozac tablets" does not offer further information about the drug itself; it simply provides information on how the drug was administered), combo words (alphanumerics like "20 mg.," for example, which are redundant because already in the database), numerics (the "20" in 20 mg. In this case, 20 is a numeric and "mg" is a noise word), marks (extraneous typographic symbols, such as brackets, dashes, and so forth). Additional aspects of this feature of the present invention are provided in U.S. Patent ~~Application Serial~~ No. [[----------]]6,778,994, ~~filed May 2, 2001,~~ entitled Pharmacovigilance Database, which is incorporated herein by reference.

Please replace paragraph [0108] with the following amended paragraph:

[0108] At the bottom of the Reaction Count and % of Reactions columns are numbers showing the number of incidents of the reactions at the Top 10 HLTs ~~(488)~~ (12,950) and the Total Reactions across all of the 256 HLTs (in this case, ~~1752~~ 62,669), 703 and 704, respectively.

Please replace paragraph [0113] with the following amended paragraph:

[0113] In this figure, the Concomitant Drugs Table 800 lists the top 10 drugs in the concomitant category. In this example, ~~hydrochlorothiazide, aspirin, and furosemide~~ Lamivudine, Didanosine

and Indivinavir Sulfate were among the drugs found in combination with ~~Candesartan Cilexetil~~ Stavudine in the adverse reactions reported to the FDA.

Please replace paragraph [0114] with the following amended paragraph:

[0114] The table divides the cases of concomitant drugs into two groups: Suspect and Non-suspect (fields 801 and 802, respectively). When an adverse reaction report is filed, certain drugs in the case may be indicated as suspect. When considering concomitant drugs, these drugs will be either suspect or not in the cases relating to the queried drug (in this case, ~~Candesartan Cilexetil~~ Stavudine). Thus, in this example there are four cases to consider, suspect and non-suspect for the queried drug, and suspect and non-suspect for the concomitant drug.

Please replace paragraph [0115] with the following amended paragraph:

[0115] In the example, ~~Hydrochlorothiazide~~ Lamivudine is the drug found to be most frequently interacting with ~~Candesartan Cilexetil~~ Stavudine. The total number of incidents (~~45~~ 12617) is broken out into the Suspect and Non-Suspect categories, and the total is also displayed as a percentage of cases that mention this concomitant drug (it is assumed a drug is only mentioned once per case), in this case ~~10.79%~~ 100 of the total number of cases involving ~~Candesartan Cilexetil~~ Stavudine. The remaining Top 10 concomitant drugs are listed in order of descending frequency.

Pleae replace paragraph [0143] with the following amended paragraph:

[0143] The Correlation Details screen of Figure 14 provides the data for each of the cases included in that pair of correlated terms. For example, if the term pair in the Correlated Terms

Screen was ~~"Female"~~ "under 16" and "Candesartan Cilexetil," this screen provides the pertinent information for all of the cases where those two terms were paired. In this example, there were ~~18~~ 6 cases where renal function analyses were correlated with Candesartan Cilexetil. For each case, preferably the following information is provided: the case ID (field 1401); the gender of the patient (field 1402); the Manufacturer's Control Code (field 1403); the FDA Report Receipt Date (field 1404); the patient's age (field 1405); the other drugs the patient was taking at the time of the incident(s) (field 1406); the patient's reaction(s) to the medications (field 1407); and ~~whether~~ the outcome ~~was serious (yes or no)~~(field 1408). By selecting these cases, the user can then profile the set of cases.

Please replace paragraph [0157] with the following amended paragraph:

[0157] The comparator or differencing engine screen in the preferred offering offers three sets of analyzed data: Pre/Post Market data, Other Post-Market Reaction, and Other Clinical Trial Reaction. An examplary comparator screen is provided in Figure 20. The Pre/Post Market data is preferably organized into a series of columns in a first table (field 2000), providing the information, including Reaction HLT (field 2001); Clinical Trial Reaction count (field 2002); Clinical Trial Percentage (field 2003), Clinical Trial Adjusted Percentage (field 2004); Post Market Reaction count (field 2005); Post Market Percentage (field 2006); Post Market Adjusted Percentage (field 2007); and Difference Ratio (field 2008). The adjusted percentages account for proportions of those reactions that are common in both pre- and post-market reporting. The second table (field 2009)lists Other Post-Market Reaction (field 2010)and each reaction's Post-Market Percentage (field 2011). This information represents data available in the integrated public database. The third table (field 2012)provides Other Clinical Trial Reaction (field

2013)and each reaction's Clinical Trial Percentage (field 2014). This information indicates whether this reaction was mentioned on the manufacturer's package insert.

Please replace paragraph [0159] with the following amended paragraph:

[0159] In viewing the results of the system and method of the present invention, when a box on a table or in a matrix or a hyperlink is selected, the case listing is generated. When a user clicks on any of the numbers, he/she is provided with a listing of each of the cases corresponding to that link. An examplary Case List is provided in Figure 21. For each case, various information is provided, including case ID (field 2100), gender (field 2101), Manufacturer Control Code (field 2102), FDS Report Receipt Date (field 2103), Age (field 2104), Drugs (field 2105), Reactions (field 2106), ~~Seriousness~~ outcomes (field 2107)~~(Y/N or normal outcome (optional))~~. These columns can be sorted by clicking on their headings. If a user selects a summary view, a profile of the cases in the case list is then calculated and displayed. Additionally, if a user wishes to learn the details of a specific case, he/she can click on the case ID number of any specific case on the correlation details screen.